

**REMARKS**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

**1. Examiner Interview**

Applicants' representatives, Andrea Small and Christian M. Bauer, along with the first named inventor, William H. Bosch, appreciate the Examiner's and Examiner Padmanabhan's time, during the personal interview of August 30, 2007. During the interview, Applicants' representatives discussed proposed claim amendments and the prior art, particularly the teachings of U.S. Patent No. 6,207,178 to Westesen et al. The discussion of the claim amendments and the prior art is formalized in the remarks below.

**2. Status of the Claims**

Claim 1 has been amended to recite the transitional phrase "consisting essentially of," which limits the scope of the claim to the specified materials or steps and those that do not materially affect the basic and novel characteristics of the claimed invention. Claim 1 has also been amended to delete the term "about."

Claims 4-7 have been amended to delete the term "about."

Claim 8 has been cancelled and incorporated into claim 1.

Claims 9 and 10 are amended for proper dependency.

Claim 11 has been amended for clarity.

Claim 12 is cancelled because Applicants do not believe that an excipient materially affects the basic and novel characteristics of the claimed invention.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested. After amending the claims as set forth above, claims 1-7, 9-11, and 13-34 are now pending in this application, with claims 15-34 withdrawn from examination.

**2. Rejection of the Claims Under 35 U.S.C. 112, 2<sup>nd</sup> paragraph**

Claims 1 and 4-7 are rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, on the grounds that the terms “less than” and “about” cannot be stated at the same time to identify a range or amount. *See* page 3 of the Office Action. Applicants have deleted the term “about” in claims 1 and 4-7. The Examiner is therefore respectfully requested to withdraw the rejection.

**3. Rejection of the Claims Under 35 U.S.C. 103(a)**

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over commonly-owned Wiedmann et al. (U.S. Patent No. 5,747,001, for “Aerosols containing beclomethazone nanoparticle dispersions”) (“Wiedmann”) in view of Westesen et al. (U.S. Patent No. 6,207,178 B1, for “Solid lipid particles, particles of bioactive agents and methods for the manufacture and use thereof”) (“Westesen”). *See* pages 3-5 of the Office Action.

**A. Summary of the Claimed Invention**

Consistent with discussions during the personal interview, claim 1 has been amended to recite the transitional phrase “consisting essentially of,” which limits the scope of the claimed sterile nanoparticulate dispersion to the specified elements in the claim and those elements that

do not materially affect the basic and novel characteristics of the sterile nanoparticulate dispersion.

**B. Summary of Westesen et al. (U.S. Patent No. 6,207,178 B1)**

Westesen is directed to solid lipid particles (SLPs) and particles of bioactive agents (PBAs). Westesen's invention focuses on the fact that the SLPs act as a carrier system for biologically active substances. The SLPs are characterized as non-spherically shaped particles composed of crystalline lipids that can provide a controlled delivery of poorly water-soluble components. *See* col. 5, lines 23-33. SLPs are lipidic particles of a solid physical state in the micrometer size range, but predominantly in the nanometer size range. *See* col. 5, lines 34-36. Their solid state exhibits better physical stability over emulsion droplets and makes them well suited for the solubilization of lipophilic and poorly water-soluble substances by entrapping them into the lipid matrix. *See* col. 5, lines 60-63 and col. 6, lines 8-10. SLPs enhance the bioavailability of the bioactive substance because the substances are solubilized in biodegradable lipid matrix and are therefore present in the dissolved state. *See* col. 6, lines 34-37. Accordingly, the SLPs of Westesen are specific elements that materially affect the basic and novel characteristics of the invention disclosed by Westesen.

**C. In Contrast to Westesen, the Claimed Invention as Amended Requires a Sterile Nanoparticulate Dispersion Consisting Essentially of a Liquid Dispersion medium, Nanoparticle, Tylopaxol, and Optionally At Least One Secondary Surface Stabilizer**

As previously stated, claim 1 has been amended to recite the transitional phrase "consisting essentially of." This limits the scope of the claim to the recited elements that make up the claimed sterile nanoparticulate dispersion, and other elements that do not materially affect the claimed invention. However, because Westesen requires SLPs as a material element, this teaching cannot be applied against the present claims as amended.

Applicants therefore respectfully submit that the combination of Wiedmann and Westesen do not teach the claimed sterile nanoparticulate dispersion. Withdrawal of the rejection and allowance of the claims is respectfully requested.

**4. Conclusion**

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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